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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,142	03/01/2002	Stephen Glanowski	CL001326	2692

22896 7590 11/02/2006

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EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT PAPER NUMBER

1631

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/085,142	Applicant(s) GLANOWSKI ET AL.	
	Examiner Karlheinz R. Skowronek	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

Claims 1-41 have been cancelled.

Claims 42-48 are newly added, pending and will be examined.

Introduction

Rejections not reiterated from the previous office action are withdrawn from consideration. The new rejections below have been necessitated by amendment of the claims.

Claim Objections

Claims 42 and 46 are objected to because of the following informalities:

Claim 42 recites a method comprising step a-g, however the letter (d) has been used twice. For the purpose of examination the second instance of (d) will be incremented to (e) and each following lettered step designation will be increased to the next letter in the alphabet.

Claim 46 recites the addition of step (h) to the steps of claim 42, in view of the mislabeling of the steps of claim 42, the step (h) of claim 46 will be incremented to (i).

Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

Claim 42 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "polymorphic analysis" is unclear in claim 42. The term is not defined by the specification and the claim does not provide a way to determine the meaning. Claims 43-48 are also rejected because they depend from claim 42, and thus contain the above issues due to said dependence.

The term "a next" in claim 42 step (e) is a relative term which renders the claim indefinite. The term "next" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Does "a next" mean adjacent, either following or preceding the one angular value? When following or preceding the one angular value does "a next" mean immediately or within a determine number of points?

The term "locality" in claim 42 step (g) is a relative term which renders the claim indefinite. The term "locality" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Does locality refer to some distance measure or some type of spatial indexing?

The term "predetermined condition" in claims 46 is unclear. The specification does not define the term. Are the "predetermined conditions" similar to the conditions

exemplified in the specification as including excess classification in one category or classification in one or more categories?

Claim Rejections - 35 USC § 112, First Paragraph

New Matter

Claims 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 46-48 are directed to identifying at least one pair of probes as undetermined based on at least one predetermined condition, the predetermined conditions being comparison of the dye emission to control probe (cl. 47) and a range between a maximum and minimum fluorescence dye emission (cl. 48). The specification does not teach the identification of undetermined probe pairs based on predetermined conditions. One of ordinary skill would not be able to assess that applicant had possession of the invention as claimed.

Enablement

Claim 42-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the identification of clusters from genotypic fluorescence data which has no overlap between potential clusters, does not reasonably provide enablement for identification of clusters from any genotypic fluorescence data in general, e.g. data for which potential clusters overlap. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The invention is drawn to a method of identifying clusters in genotypic fluorescence data by determining the angular values derived from calculating the arctangent of the plotted points sorting the angular values, sorting the angular values and calculating a set of difference values from the set of angular values, determining a

category dividing angular value from the set of difference values by comparison to a threshold and determining a classification for the genotype based on the identified categories dividing values. The method relies on the separation of data points such that the difference in angular values is distinguishable, i.e. greater than a category-dividing threshold difference. The method is thus dependent on the successful determination of the "predetermined category-dividing threshold". The specification fails to provide the guidance to the predetermination of the category-dividing threshold as it relates to data containing vague or overlapping clusters. The specification also does not provide any example for using the method to identify clusters from overlapping data. For example, the data of figure 5a provided in Rao et al. (NAR, Vol. 31, No. 11, e. 66, p. 1-8) demonstrate overlapping data for which the instant method does not seem to be enabled. Figure 5a shows scatter plotted fluorescence data where overlap occurs between 2 clusters. Based on the instantly claimed method, the difference between these clusters would be overlooked because the sorted angular values would fail to produce a difference greater than the threshold. It would require undue experimentation to use the method commensurate with the scope of the claims because to do so would require one of ordinary skill in the art to develop additional methodologies and techniques to identify clusters that are suitable for analysis with the instantly claimed method. Claims 43-48 also rejected because they depend from claim 42, and thus contain the above issues due to said dependence.

Conclusion

A diligent search of electronic patent and scientific literature data bases revealed no prior art teaching the analysis of genotyping data or Single nucleotide polymorphism data by deriving angular values from the ratios of labeled probe pairs and determining the clustering of the data by identifying cluster-separating angular values. The prior art teaches methods of identifying clusters in data using a variety of statistical techniques and metrics.

No claims allowable

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karlheinz R. Skowronek/

KRS


MICHAEL BORIN, PH.D
PRIMARY EXAMINER

